REMARKS

Claims 1-10 are pending in the present application.

The rejection of Claims 1-10 under 35 U.S.C. §103(a) over Egberink et al (WO 02/45753) in view of Schor et al (US 4,369,172) is respectfully traversed.

Egberink et al disclose pharmaceutical formulation that comprises gepirone hydrochloride, a cellulosic polymer, and a microcrystalline cellulose (page 1, lines 4-7). The Examiner further cites Example 1 as disclosing a tablet composition with gepirone HCl dosages ranging from 40 mg to 80 mg and HPMC levels ranging from 70 to 75% (citing page 4, lines 15-19). Citing page 5, line 29, the Examiner asserts that the compressed tablets are stored in tight containers until further use or testing.

Applicants submit that, as the Examiner recognizes, Egberink et al fail to disclose or suggest the water activity of the tablet. Applicants further submit that Egberink et al fail to disclose or suggest packaging such as to delay moisture uptake by the tablet.

The Examiner alleges that "the limitation of a packaged tablet and the limitation of delaying moisture uptake would have been obvious over the tablets that are stored in tight containers, as taught by Egberink (Page 5, line 29). One skilled in the art would optimize the stability of the tablets by protecting them from moisture and would use blister packs, foil packs, bottles, desiccants, and other packaging materials used in the art to prevent moisture uptake by contents." Applicants disagree.

Applicants submit that the claimed feature of "*is maintained to have a water activity of at most 0.6*" or the corresponding language in Claim 3 related to a water content of less than 9% w/w is critical to the claimed invention as shown in Table 2 on page 7 of the present application. As shown in this table, when the water activity increases above this threshold

value the tablet becomes vulnerable to dust formation. Such a result and the threshold value is not disclosed, suggested, or even realized in either Egberink et al or Schor et al. Moreover, there is no evidence of record that the "tight containers" disclosed by Egberink et al provide sufficient protection from moisture. Even if "tight containers" do provide some protection against moisture, such protection is less than hermetic containers, for example. Further, without any realization as to the threshold water activity or water content to remain below, there is nothing in Egberink et al or Schor et al to show how the container would satisfy this requirement.

In other words, the tight containers in which the tablets comprising gepirone HCl (40, 60 or 80 mg) and 75% hydroxypropyl methylcellulose are packaged provide no measure of suggestion that these containers are to be used to maintain the tablet water activity of at most 0.6 (or the tablet water content of less than 9% w/w), even assuming that the original water activity was below this threshold. Further, there is no basis to conclude that the tablets disclosed in Egberink et al originally have a water activity of at most 0.6 or water content when the tablets are leaving the tablet compression machine.

Schor et al to discloses tablets comprising 57% HPMC (column 4, line 25) and a moisture content of 4,5-5,5% (column 4, lines 50-51). The present invention differs from Schor et al to by the fact that the tablets disclosed in the present invention are maintained to have a water activity of at most 0.6 (or a water content of less than 9% w/w). By decreasing the relative humidity storage condition (page 2, lines 1-3) provides an advantage in a reduction of dust formation during handling tablets (page 1, lines 31-33). There is no such suggestion in Schor et al to control the water activity in this way.

When viewing the combined disclosures of Egberink et al and Schor et al, the skilled artisan would not be prompted to control the water activity (or the water content) by

maintaining it to a reduced level in order to avoid dust formation. Indeed, the moisture contained in the tablet can be used to maintain the cohesion in the tablet and thus an increase of the moisture content of the tablets once they are leaving the tablet compression machine would be considered favorably by the one skilled in the art not to have dust formation.

Accordingly, the combined disclosures of Egberink et al and Schor et al fail to offer any suggestion that the water activity level (or water content) should be controlled to control dust formation, what water activity level (or water content) would be the practical threshold, or how the tablet may be maintained to not exceed this threshold. Therefore, Applicants submit that this ground of rejection is not tenable and should be withdrawn.

Withdrawal of this ground of rejection is requested.

The objection to Claims 6, 8, and 9, as well as the objection to the specification, as containing typographical errors are obviated by amendment. Applicants have amended the specification and claims to address the Examiner's specific criticisms.

Withdrawal of these grounds of objection is requested.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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